UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,376	07/28/2001	Shi-You Ding	NREL 01-36	9956

30955 7590 04/18/2006

LATHROP & GAGE LC
4845 PEARL EAST CIRCLE
SUITE 300
BOULDER, CO 80301

EXAMINER	
SWOPE, SHERIDAN	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/917,376	DING ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-9,12,14,15,28,30-36,43 and 47-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-9,12,14,15,28,30-36,43 and 47-56* is/are rejected.

7)☒ Claim(s) *47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response, on February 8, 2006 to the Action on the Merits of this case mailed November 8, 2005, is acknowledged. It is acknowledged that applicants have cancelled Claims 10 and 11, amended Claims 1, 4-9, 12, 14, 28, 43, and 47-54, and added Claims 55 and 56. Claims 1, 2, 4-9, 12, 14, 15, 28, 30-36, 43, 47-56 are pending and are hereby considered.

Claims-Objections

Claim 47 is objected to for "wherein said catalytic domain of GH74_Ace having a sequence", which should be corrected to "wherein said catalytic domain of GH74_Ace has a sequence".

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of Claims 1, 2, 4-9, 14, 15, and 47-54 under 35 U.S.C. 112, second paragraph, for the reasons set forth in the Final Rejection of May 18, 2005, because the phrase "carbohydrate binding domain (CBD)III" renders the claims indefinite is withdrawn for the following reasons. Tormo et al, 1996 provide teachings, including crystal structures, which enable the skilled artisan to recognize the metes and bounds of a CBDIII.

Rejection of Claims 2, 4, 5, 7-9, 49, and 52 under 35 U.S.C. 112, second paragraph, for the reasons set forth in the Final Rejection of May 18, 2005 and the prior action, because the phrases "a catalytic domain of a glycosyl hydrolase family 74 (GH74_Ace) enzyme" renders the claims indefinite is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments. (i) It is indisputable that the art well recognizes the

features of GH74 family domains. (ii) The Court states that Applicant need not specifically teach what is well-known. (iii) Applicant has described species of GH74 family domains, i.e., SEQ ID NO: 1 and 3.

These arguments are not found to be persuasive for the following reasons. (i) Neither the specification nor Applicants' rebuttal provide evidence that the structure of the GH74 family domain is well defined. Furthermore, searching the prior art databases did not provide guidance, from the prior art, as to the metes and bounds of the recited invention (see encloses searches of STN and PubMed). (ii) It is acknowledged that the specification need not disclose that which is well-known. However, for the reasons set forth in the prior actions and in (i) above, the structure of the GH74 family domain is not well defined. (iii) It is acknowledged that the specification teaches two species of the recited domain; however, said species is not sufficient to define the metes and bounds of the recited invention. For these reasons and those provided in the prior actions, rejection of Claims 2, 4, 5, 7-9, 49, and 52 under 35 U.S.C. 112, second paragraph, is maintained.

Rejection of Claim 31 under 35 U.S.C. 112, second paragraph, for the reasons set forth in the prior actions, because the phrase "substrate targeting moiety" renders the claims indefinite is maintained. In support of their request that said rejection be withdrawn, Applicants state that that the specification, on page 9, defines "substrate" as "a polymer such as cellulose or can be a complex molecule or aggregate of molecules where the entire moiety comprises at least some cellulose". Said "definition" is indefinite because it is only exemplary and does not define the metes and bounds of the recited invention.

For Claim 6, as amended, the phrase "a polypeptide sequence of SEQ ID NO: 3" renders the claim indefinite. It is unclear whether the claim is meant to recite "the" polypeptide of SEQ ID NO: 3 or "any" polypeptide of SEQ ID NO: 3. The latter would encompass peptides as small as two residues. Clarification is required. For purposes of examination, it is assumed that Claim 6 is meant to recite the polypeptide sequence of SEQ ID NO: 3.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Rejection of Claims 28, 30-36, and 43 under 35 U.S.C. 112, first paragraph, for lack of enablement, as set forth in the prior actions, is maintained. As stated in the prior action, the specification is not enabling for Claims 28, 30-36, and 43, which are so broad as to encompass any polypeptide having at least 99% identity to SEQ ID NO: 1, 3, 4, or 5 and having any activity. In support of their request that said rejection be withdrawn, Applicants provide the following arguments. (i) That they disagree with the Examiner for the reasons explained in the prior responses. (ii) The claims now recite 99% sequence identity. It is not necessary that every permutation be effective in order for the inventor to obtain a generic claim.

These arguments are not found to be persuasive for the following reasons. (i) Applicants are referred back to the Examiner's responses to their prior arguments. (ii) It is acknowledged that the claims now recite 99% sequence identity. However, without a recitation of the desired activity, the skilled artisan would not know how to make and use the desired invention. For

these reasons and those provided in the prior actions, rejection of Claims 28, 30-36, and 43 under 35 U.S.C. 112, first paragraph, for lack of enablement, is maintained.

Written Description

Claims 1, 2, 4-9, 12, 14, 15, 28, 30-36, 43, 47-51, and 53-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claims 1, 2, 4-9, 12, 14, 15, 47, and 48 introduce the limitation of a polypeptide having "at least 99% sequence identity with SEQ ID NO: 1". Claims 28, 30-36, 43, and 55 introduce the limitation of a polypeptide having "at least 99% sequence identity with SEQ ID NO: 1, 3, 4, or 5". Claims 49-51 and 54 introduce the limitation of a polypeptide having "at least 95% sequence identity with SEQ ID NO: 1". Claims 53 and 56 introduce the limitation of a polypeptide having "at least 99% sequence identity with SEQ ID NO: 3". Said limitations are not disclosed in the original specification or claims. Thus, Claims 1, 2, 4-9, 12, 14, 15, 28, 30-36, 43, 47-51, and 53-56 are rejected under 35 U.S.C. 112, first paragraph, for introducing New Matter.

Rejection of Claims 28, 30-36, and 43 under 35 U.S.C. 112, first paragraph, for insufficient Written Description, is maintained. The specification does not contain a disclosure of the function of all polypeptides having at least 99% identity to SEQ ID NO: 1, 3, 4, or 5. The instant rejection was previously explained in the Action on the Merits of June 16, 2004 and the Final Rejection of May 18, 2005. Applicants did not response to this rejection.

Rejection of Claims 47, 48, 50, 51, and 54, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained. As explained in the prior action, the original specification and claims fail to disclose the limitation of "identical to SEQ ID NO: 3 in each conserved position marked by an asterisk (*), as shown in the comparison

to *Aspergillus aculeatus* Avicelase III(AviIII_Aace):", as recited in said claims. Applicants did not response to this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of Claims 1, 2, 4-12, 14, 28, 36, 43, and 47-54 under 35 U.S.C. 102(b) as being anticipated by Adney et al, 1994 or Tucker et al, 1989, for the reasons set forth in the prior actions, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(A) There is no evidence, at the time of the invention, that A. celluloyticus comprises a gene encoding the polypeptide of SEQ ID NO: 1 or that said polypeptide would be expressed under the conditions of Adney or Tucker. It was not until the present invention, that it became known that the polypeptide of SEQ ID NO: 1 has a signal sequence. Applicant doesn't understand why the Examiner insists that a person of ordinary skill in the art would believe that the culture supernatant in Adney or Tucker, more likely than not, contains the claimed purified polypeptide of SEQ ID NO: 1.

(B) According to Examiner's rationale, if someone in the past has collected all human blood cells and homogenize them into a mixture of thousands of molecules, no patents would be issued to inventors who later identify novel purified sequences of hormones, cytokines, and cell

surface receptors expressed by human blood cells, because all these novel molecules more likely than not exist in the cell homogenate.

(C) The present claims are not anticipated by Adney or Tucker because neither reference teaches all the limitation of the amended claims.

(D) The culture supernatant of Adney or Tucker was a crude mixture of many proteins and Examiner has provided no evidence that the culture supernatant had been purified within the meaning of the present invention.

These arguments are not found to be persuasive for the following reasons. It is acknowledged that

(A) Reply: The protein of SEQ ID NO: 1 is derived from A. celluloyticus. Both Adney et al and Tucker et al teach harvested culture supernatant from A. celluloyticus grown under conditions that would support secretion of proteins with signal sequences. It is not necessary for the art to teach that the protein of SEQ ID NO: 1 has a signal sequence; the protein of SEQ ID NO: 1 would, inherently, be contained within said culture supernatant.

(B) Reply: The Examiner is not in a position to comment on hypothetical claims. However, Claims 1, 2, 4-12, 14, 28, 36, 43, and 47-54, reciting a compositions comprising the polypeptide of SEQ ID NO: 1 is anticipated by Adney et al, 1994 or Tucker et al, 1989.

(C) Reply: All of the Claims 1, 2, 4-12, 14, 28, 36, 43, and 47-54 encompass a composition comprising the polypeptide of SEQ ID NO: 1 and, therefore, are anticipated by Adney et al or Tucker et al.

(D) Reply: The specification defines "'Purify' or 'purified'" as "a target protein that is free from at least 5-10% of contaminating protein" (pg 12, lines 12-13). Therefore, the culture supernatants of Adney et al or Tucker et al anticipate the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Rejection of Claims 1, 2, 4-9, 12, 14, 15, 28, and 47-54 under 35 U.S.C. 103(a) as being unpatentable over Mohagheghi et al, 1986 in view of Berghem et al, 1976 and Katz et al, 1968, for the reasons described in the First Action on the Merits of August 1, 2002, the Final Rejection of March 11, 2003, the RCE First Action on the Merits of June 16, 2004, the RCE Final Rejection of May 18, 2005, and the RCE First Action on the Merits of November 8, 2005 is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(E) The Office has not shown a *prima facie* case of obviousness, which requires all the claim limitations to be taught or suggested by the prior art. No reference teaches or suggests the *exoglucanase* GH74 family polypeptide that is taught. Berghem et al show the isolation of an *endoglucanase*.

(F) Applicant presented reasoning in the last response that the instant references, together, do not teach or suggest purification of the enzyme to the extent disclosed by the instant application.

(G) By disclosing the coding sequence of SEQ ID NO: 1, the present invention enables one to over express AviIII in a heterologous host cell. Without a showing of purity commensurate with that of the present invention, the references do not provide enabling methodology.

These arguments are not found to be persuasive for the following reasons.

(E) Reply: This is the same argument that Applicants presented in their response of December 26, 2002, June 23, 2003, March 3, 2005, and September 2, 2005. Applicant is referred back to the Office's responses of March 11, 2003, June 16, 2004, May 18, 2005, and November 8, 2005. In brief, the methods taught by Berghem et al would be successful in isolating the polypeptide of SEQ ID NO: 1 from the cell taught by Mohagheghi et al and Katz et a provide motivation for doing so.

(F) Reply: Applicant is referred back to the Office's response to said "reasoning".

(G) Reply: The specification does not disclose purification of the polypeptide set forth by SEQ ID NO: 1. It is acknowledged that the specification does disclose the coding sequence for SEQ ID NO: 1 and enables the skilled artisan to over express AviIII in a heterologous host cell. However, the instant rejection is not under 35 USC 112 for lack of enablement, but under 35 USC 103(a) for being render obvious by the combination of Mohagheghi et al in view of Berghem et al and Katz et al. Furthermore, the instant claims to not recite the polypeptide of SEQ ID NO: 1 purified from a recombinant host cell but in a composition comprising the purified polypeptide, wherein the specification defines "'Purify' or 'purified'" as "a target protein that is free from at least 5-10% of contaminating protein" (pg 12, lines 12-13).

For these reasons and those provided in the prior actions, rejection of Claims 1, 2, 4-9, 12, 14, 15, 28, and 47-54 under 35 U.S.C. 103(a) as being unpatentable over Mohagheghi et al, 1986 in view of Berghem et al, 1976 and Katz et al, 1968, is maintained.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

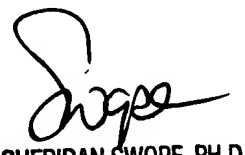
To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that Applicants identify support, within the original application, for any amendments to the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
Art Unit 1656



SHERIDAN SWOPE, PH.D.
PRIMARY EXAMINER